

Patent
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II. THE REJECTION UNDER §102 IS OVERCOME

Claims 65, 68, 81 and 82 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Zanetti *et al.* The rejection is traversed.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the references relied upon by the Office Action do not disclose, suggest or enable Applicants' invention. The Office Action states that the complex defined in claim 65 lacks novelty over Zanetti (US 5,583,202) because the binding region of the equivalent bifunctional molecule in Zanetti comprises "an antigen of *P. falciparum*". It is respectfully submitted that the Examiner has misinterpreted Zanetti, which concerns a complex comprising:

- (i) a mouse monoclonal antibody [Sp-3-B4] whose specificity is directed against the (NANP)₃ epitope from the parasite *Plasmodium falciparum*; and
- (ii) an engineered antibody [y1NANP] to which the *P. falciparum* epitope (NANP)₃ has been introduced as a foreign epitope into the CDR3 region of the H chain of the mouse/human chimera Cy161.

The purpose of the Zanetti complex was to demonstrate that the y1NANP expresses the (NANP)₃ epitope in an immunologically accessible form.

In contrast, claim 65 of the present application defines a complex comprising:

- (i) *an antibody derived from a first species*

In the Zanetti complex, this antibody is equivalent to the y1NANP antibody.

- (ii) *a bifunctional molecule comprising a binding region of a non-antibody origin which binds to the antibody of the first species or to one or more groups provided thereon*

In the Zanetti complex, the bifunctional molecule would be equivalent to the mouse monoclonal antibody SP-3-B4. Clearly, the binding region of this mouse monoclonal antibody is of antibody origin.

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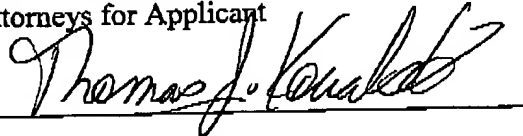
Accordingly, the complex described by Zanetti does not fall within the scope of the present application. Indeed, the complex defined in claim 65 is clearly novel over the complexes disclosed in the cited art in that the binding region of the bifunctional molecule is of non-antibody origin. On the contrary, the complexes of the publications cited in the Office Action involve antibodies or parts thereof. The cited references do not teach, suggest, or enable a bifunctional molecule in which the immunoglobulin constant region is not a naturally occurring F_C fragment. Therefore, reconsideration and withdrawal of the Section 102 rejection are believed to be in order and such action is respectfully requested.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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